March 25, 2013

Revision E



National Aeronautics and Space Administration Lyndon B. Johnson Space Center Houston, Texas 77058

March 25, 2013

PREFACE

HUMAN RESEARCH PROGRAM, SCIENCE MANAGEMENT PLAN

The purpose of this document is to describe the policies and guidelines utilized in the management of the science within the Human Research Program (HRP). The need to produce a Science Management Plan is established in the HRP Program Plan (HRP-47051), and is under configuration management control of the HRP Science Management Panel (SMP) and the HRP Control Board (HRPCB).

Approved By:			
original signature on file	March 25, 2013		
William H. Paloski, Ph.D.	Date		
Program Manager			
Human Research Program			

March 25, 2013

ared By:	
original signature on file	March 25, 2013
Lisa P. Stephenson, MBA, PMP Book Manager Deputy Manager, HRP Science Management Office	Date
curred By:	
original signature on file	March 25, 2013
Craig E. Kundrot, Ph.D. Chief Scientist, Acting Human Research Program	Date

REVISION AND HISTORY PAGE

REV.	DESCRIPTION	PUB. DATE
Baseline	Baseline approved by HRPCCB per SLSDCR-HRPCB-07-001	02/09/07
Rev. A	Revised by HRPCCB per SLSDCR-HRPCB-07-011	05/30/07
Rev. B	Revised by HRPCB per SLSDCR-SMP-07-012	10/24/07
Rev. C	Revised by HRPCB per SLSDCR-SMP-08-007, SLSDCR-SMP-08-012, and SLSDCR-HRPCB-08-022	12/11/08
Rev. D	Revised by HRPCB per SLSDCR-SMP-11-002, and SLSDCR-HRPCB-11-007	05/12/11
Rev. E	Revised by HRPCB per SLSDCR-HRPCB-12-021 and SLSDCR-HRPCB-12-021-R1	03/25/13

TABLE OF CONTENTS

1.0	I	NTRODUCTION	1
	1.1	Purpose	1
	1.2	Scope	
	1.3	Document Authority	
	1.4	Management Authority	
	1.5	Applicable Documents	
	1.6	Reference Documents	3
2.0	P	ROGRAM RESEARCH CONTENT OVERVIEW	3
	2.1	Background	3
	2.2	Elements, Project, Portfolios	
	2.3	The National Space Biomedical Research Institute	
	2.4	Research Activities Contributing to HRP	
		2.4.1 NASA Small Business Innovative Research	
		2.4.2 NASA Experimental Program to Stimulate Competitive Research	
		2.4.3 Open Innovation	6
3.0	S	CIENCE MANAGEMENT ROLES AND RESPONSIBILITIES	7
	3.1	Chief Scientist	8
	3.2	Deputy Chief Scientist	11
	3.3	Manager, Science Management Office	11
	3.4	Chief, International Science Office	11
	3.5	Element Scientist	13
	3.6	Deputy Element Scientist	14
	3.7	Project/Portfolio Lead Scientist	
	3.8	Conflict of Interest	16
4.0	S	CIENTIFIC COORDINATION PANELS	16
	4.1	HRP Science Management Panel	16
	4.2	Project or Portfolio Investigator Working Groups	17
	4.3	NASA-NSBRI Steering Committee	17
5.0	R	ESEARCH PLANS	17
	5.1	Integrated Research Plan	18
	5.2	Evidence Base	
		5.2.1 Human Research Roadmap	19
		5.2.2 Human Health and Performance in Space portal	
		5.2.3 Human Research Wiki	19
6.0	R	ESEARCH AND TECHNOLOGY PROPOSALS	19
	6.1	Sources of Proposals	20
		6.1.1 Solicited Proposals	20
		6.1.1.1 Announcement of Opportunity	20

			LIST OF ACDONVMS	T 1
			TEMPLATE FOR WRITTEN DISSENTING SCIENTIFIC OPINION	
API	PENDI	IX D.	RESEARCH PLAN TEMPLATE FOR THE HRP ANNUAL CYCLE	
API	PEND	IX C.	GENERAL GUIDELINES FOR DEVELOPING THE INTEGRATED	~ .
API	PEND	IX B.	COUNTERMEASURE AND TECHNOLOGY READINESS LEVELS	B-2
API	PEND	IX A.	RESEARCH CATEGORY DEFINITIONS	A-1
	10.2	Resol	lution of Scientific Dissent	32
	10.1	Proce	ess for Addressing Scientific Dissent	31
10.0) D]	ISSEN	TING SCIENTIFIC OPINION	 3 1
	9.3		nical Reviews	
	9.2		omer Supplier Agreements	
	9.1	Techi	nology Development Projects	29
9.0	Tl	ECHN	OLOGY DEVELOPMENT PROCESS	28
	8.2	Elem	ent Data Management Plan	28
	8.1	Life S	Sciences Data Archive	28
8.0	\mathbf{D}_{A}	ATA N	MANAGEMENT	28
	7.7	Pre-d	elivery Acceptance Review	27
	7.6		and Evidence Review	
	7.5		am Status Review	
	7.4	_	al HRP Investigators' Workshop	
	7.3		am Science Review	
	7.1		ling Review Panels	
	7.1		pline Science Review	
7.0	R	EVIEV	WS	25
	6.5		osal Selection and Funding	
	6.4	Confl	lict of Interest in Reviews and Evaluations	
		6.3.3		
		6.3.2	•	
	6.3	6.3.1	osal Evaluation	
	62	6.2.3	.	
		6.2.2	1	
		6.2.1		
	6.2	Gene	ral Proposal Format	23
		6.1.3	•	
		6.1.2	*	
			.1.1.4 Request for Proposals/Information	
			.1.1.2 NASA Research Announcement	
		6	.1.1.2 NASA Research Announcement	•

List of Figures

FIGURE 1.	STRUCTURE OF ELEMENTS, PORTFOLIOS AND PROJECTS WITHIN THE HRP	5
FIGURE 2.	HRP SCIENCE MANAGEMENT RELATIONSHIPS	8
FIGURE 3.	HRP Procurement Process	20
FIGURE D-1.	TEMPLATE FOR HRP ANNUAL CYCLE	D-2

1.0 INTRODUCTION

1.1 PURPOSE

The purpose of this document is to describe the policies and guidelines utilized in the management of the research and technology development portfolio of the Human Research Program (HRP). The HRP is an applied research and technology development program managed at the Johnson Space Center (JSC) that addresses the National Aeronautics and Space Administration (NASA) needs for human health and performance risk mitigation strategies in support of space exploration missions. The HRP is focused on research and technology development that addresses high priority risks to astronaut health and performance with the goal of providing countermeasures, knowledge, technologies, and tools to enable safe, reliable, and productive human space exploration. The HRP is part of the Space Life and Physical Science Research Applications Division (SLPSRA) located within the Human Exploration and Operations Mission Directorate (HEOMD) at NASA Headquarters.

NASA's space exploration missions may include missions to the Moon, Earth-Moon Lagrange points, near Earth objects, and Mars. Although these mission destinations involve some of the same human health and performance challenges, each also includes specific challenges that depend on the nature of the mission and the mission development schedule. The HRP research and technology development is phased to supply appropriate deliverables in time to meet the challenges of each mission type as it occurs. An important component of the HRP involves research on the International Space Station (ISS), a unique laboratory environment in low Earth orbit that enables the collection of in-flight data necessary for space exploration mission risk reduction. The HRP utilizes the ISS to the maximum extent possible to perform the essential research and technology development tasks that can only be done in spaceflight.

1.2 SCOPE

The policies referenced in this document apply to all ground-based and spaceflight research and technology development activities of the HRP, whether those activities take place at NASA Field Centers, at universities, at non-profit research institutes, or at for-profit industries. Further information concerning the goals, objectives, customers, stakeholders, general organization and management of the HRP may be found in the Human Research Program Plan (HRP-47051).

1.3 DOCUMENT AUTHORITY

The HRP Program Plan (HRP-47051) defines the need to document the HRP science management policies in the HRP Science Management Plan. This plan is compliant with NASA Procedural Requirement (NPR) 1080.1A, Requirements for the Conduct on NASA Research and Technology (R&T) (http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=1080&s=1A), NPR 5800.1E, NASA Grant and Cooperative Agreement Handbook (http://prod.nais.nasa.gov/pub/pub_library/grcover.htm), as updated and amended by the active

Grant Information Circulars (https://www.nssc.nasa.gov/grantstatus/GIC-11-01-Transparency-

<u>Act-(FINAL).pdf</u>), and with NPR 7120.8, NASA Research and Technology Program and Project Management Requirements

(http://nodis3.gsfc.nasa.gov/displayDir.cfm?Internal_ID=N_PR_7120_0008_).

1.4 MANAGEMENT AUTHORITY

The NASA governance model defines two basic authority processes, the programmatic authority process and the technical authority process. Management of the HRP falls within the programmatic authority process of NPR 7120.8. The HRP Program Plan (HRP-47051), Section 1.4, describes the decision authority and details the management and reporting structures under which the HRP operates.

The HRP is also strongly connected to one of NASA's three technical authority processes, that of the Health and Medical Technical Authority (HMTA). The NASA Administrator has assigned HMTA responsibility to the NASA Chief Health and Medical Officer (CHMO) 80771201MED. Thus, the CHMO is responsible for the development, implementation and maintenance of standards for levels of medical care as well as the health and performance status of crewmembers during spaceflight (see NPR 8900.5B NASA Health and Medical Policy for Human Space Exploration (http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPD&c=8900&s=5A)

With the goal of increasing efficiency, the CHMO has assigned responsibility for implementing an effective HMTA process in support of the vehicle and mission definition and development to the JSC Chief Medical Officer (CMO), JSC Technical Authority Implementation Plan, Health and Medical (JPR 7120.11). It is the responsibility of the JSC CMO to ensure technical expertise is being provided to each program and project, and to provide a path to escalate technical concerns in an independent authoritative path. The JSC CMO is also responsible for ensuring support is provided to programs and projects in order to develop requirements that are in alignment with NASA standards. These human health, performance and medical standards for spaceflight guide the HRP with regard to the initiation and development of research that produces operationally relevant deliverables and informs the development or modification of spaceflight.

1.5 APPLICABLE DOCUMENTS

HRP-47051, Human Research Program Plan (HRP-47051)

NPR 1080.1, NASA Procedural Requirement (NPR) Requirements for the Conduct on NASA Research and Technology (R&T)

NPR 7120.8, NASA Research and Technology Program and Project Management Requirements

NASA-STD-3001, Space Flight Human System Standard Volume 1, Crew Health

NASA-STD-3001, Space Flight Human System Standard Volume 2, Human Factors, Habitability and Environmental Health

NASA/SP-2010-3407, Human Integration Design Handbook (HIDH)

1.6 REFERENCE DOCUMENTS

NPR 5800.1, NASA Grant and Cooperative Agreement Handbook NPR 8900.5, NASA Health and Medical Policy for Human Space Exploration JPR 7120.11, JSC Technical Authority Implementation Plan, Health and Medical HRP-47069, HRP Unique Processes, Criteria and Guidelines

2.0 PROGRAM RESEARCH CONTENT OVERVIEW

2.1 BACKGROUND

The Exploration Systems Mission Directorate (ESMD), predecessor directorate to the HEOMD, has defined the top-level requirements for the HRP which are located in the Exploration Architecture Requirements Document (EARD) - ESMD-EARD-08-07:

- NASA's Human Research Program shall develop knowledge, capabilities, countermeasures, and technologies to mitigate the highest risks to crew health and performance and enable human space exploration [Ex-0061]
- NASA's Human Research Program shall provide data and analysis to support the definition and improvement of human spaceflight medical, environmental and human factors standards [Ex-0062]
- NASA's Human Research Program shall develop technologies to reduce medical and environmental risks and to reduce human systems resource requirements (mass, volume, power, data, etc.) [Ex-0063]

The human health and performance risks associated with the EARD requirements are identified and assigned to the HRP by the Human System Risk Board (HSRB). The JSC CMO established the HSRB to ensure that a consistent, integrated process is established and maintained for managing human system risks. The EARD requirements are merged with applicable HSRB human system risks forming requirements of the HRP documented in the HRP Program Requirements Document (HRP-47052, http://www.nasa.gov/pdf/559800main_HRP-47052.pdf). Each of the defined risks is then assigned to one of the HRP's Elements (Section 2.2) for appropriate action. Several actions are possible, including: development of recommendations to avoid the risk by operational rules; new research to obtain knowledge or develop technology to fill a gap; development of appropriate countermeasures to address a mitigation gap. These activities are carried out as individual tasks assigned to Projects or Portfolios within the appropriate HRP Element.

Note: The EARD has recently been rescinded by HEOMD, and a replacement document is in work. It is anticipated that a new document will contain similar, top-level exploration architecture requirements to those listed above, which will flow to the HRP. The HRP Science Management Plan will be updated to account for any guidance changes associated with the issuance of the EARD replacement document.

2.2 ELEMENTS, PROJECTS, PORTFOLIOS AND TASKS

The HRP's activities are distributed among six specific Elements, each of which is focused on a subset of the research and technology development activities or the core service activities, as illustrated in Figure 1 below. Some Elements consist of a single Project, while others consist of multiple Projects or Portfolios. (Reference NPR 7120.8 for details on Projects and Portfolios). Integration across the Projects or Portfolios within an Element is the responsibility of the Element Scientist. Integration across the Elements is the responsibility of the HRP Chief Scientist. All research tasks in the HRP are assigned to a Project or Portfolio within one of the Elements; if multiple Projects or Portfolios do not exist within an Element, then research tasks are managed directly by the Element. While funding for the National Space Biomedical Research Institute (NSBRI, Section 2.3) cooperative agreement is centralized through NSBRI management, the NSBRI researchers communicate and coordinate with their NASA HRP counterparts within the Elements to ensure that research is complementary and synergistic.

Figure 1 also shows that HRP research and technology development activities consist of two categories: applied research and technology development activities, and core service activities - see Appendix A for a definition of these activities. Such a categorization facilitates the definition of science management processes and allows for maximum efficiency in managing associated research activities through integration of resources.

The HRP Elements are:

- Behavioral Health and Performance
- Exploration Medical Capability
- Human Health Countermeasures
- ISS Medical Projects
- Space Human Factors and Habitability
- Space Radiation

These Elements are described further in the HRP Program Plan (HRP-47051).

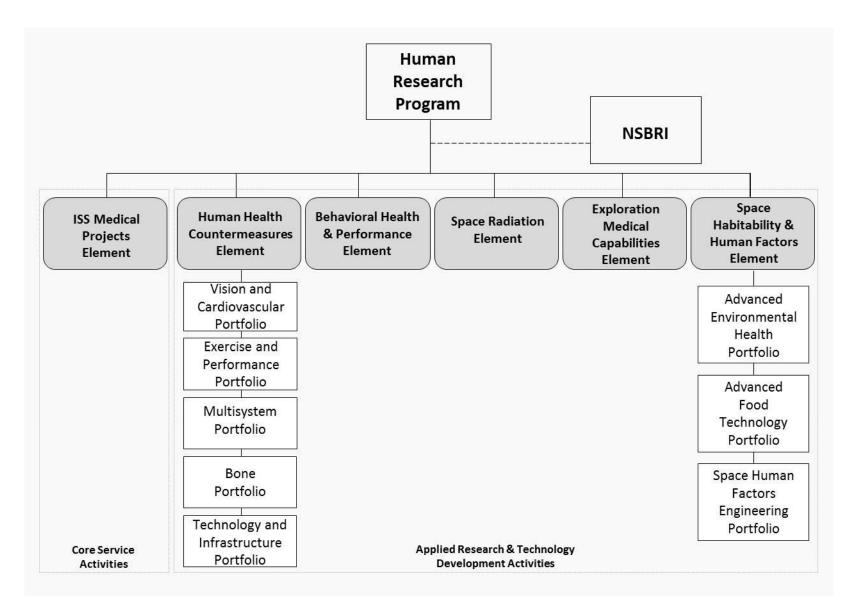


Figure 1. The general structure of Elements, Portfolios and Projects within the HRP.

Note: Since organizations change from time to time, this figure should be considered illustrative only.

2.3 THE NATIONAL SPACE BIOMEDICAL RESEARCH INSTITUTE

The National Space Biomedical Research Institute (NSBRI, http://www.nsbri.org/) is a significant research component of the HRP. Operating under a cooperative agreement with NASA, the NSBRI was formed in 1997 and is an important partner in defining, selecting and conducting research associated with space exploration mission risks; this agreement allows the NSBRI to function as an important, synergistic component of the HRP. A consortium of 12 member institutions, the NSBRI represents a unique partnership between the academic biomedical community and NASA. NSBRI researchers are working to close knowledge, countermeasure and technology gaps in all of the major discipline areas required to support human health and performance for space exploration. The NSBRI contributes to defining risk areas, identifying and demonstrating candidate countermeasures, developing medical technologies and maintaining discipline-level expertise. The NSBRI develops their strategy in coordination with the HRP Elements regarding which risks and gaps they will focus their research efforts.

Jointly, NASA and the NSBRI plan annual solicitations targeted at research and technology development that reduces human-related exploration risks and is aligned with HRP's stated goals and objectives. NASA and NSBRI are committed to maximizing the return on research investments through open communication and dialog concerning human health and performance risks.

2.4 OTHER RESEARCH ACTIVITIES CONTRIBUTING TO THE HRP

In addition to the research and technology development funded directly by the HRP, there are several resources the program leverages; three examples of these resources are the NASA Small Business Innovation Research (SBIR) program, the NASA Experimental Program to Stimulate Competitive Research (EPSCoR) and Open Innovation Service Providers.

2.4.1 NASA Small Business Innovative Research

The NASA SBIR program was established by Congress in 1982 to provide increased opportunities for small businesses to participate in research and development. The SBIR and related Small Business Technology Transfer (STTR) programs are ways to contribute to HRP's research and technology development activities. Additional information about these programs is provided at http://sbir.gsfc.nasa.gov/SBIR/SBIR.html.

2.4.2 NASA Experimental Program to Stimulate Competitive Research

The NASA EPSCoR provides states possessing modest research infrastructure with funding to develop a more competitive research base within their state and member academic institutions. Nineteen states are eligible to participate in this program. For additional information, see http://www.nasa.gov/offices/education/programs/national/epscor/home/index.html

2.4.3 Open Innovation

Open Innovation establishes service providers who use their network of solvers to help seekers (e.g., Human Health and Performance Directorate – HH&P) address HRP research and technology development gaps. This mechanism allows NASA to obtain innovative research and

HRP-47053E

technology development solutions through the extended community. For additional information, see http://www.nasa.gov/open/plan/open-innovation.html.

3.0 SCIENCE MANAGEMENT ROLES AND RESPONSIBILITIES

As described in the Human Research Program Plan (HRP-47051), responsibility for the HRP science management, planning, coordination and integration across the program is delegated to the HRP Chief Scientist. The HRP Science Management Office (SMO) supports the HRP Chief Scientist in carrying out these responsibilities.

In order to ensure the HRP deliverables can be ready in time to support NASA's space exploration mission needs, the HRP applies project management principles to the management of all HRP research and technology development activities. Project and Portfolio Lead Scientists are responsible for the scientific content and direction within their Project or Portfolio, and Element Scientists are responsible for the scientific management, planning, coordination and integration across all Projects or Portfolios within their Element. The Element, Project and Portfolio Managers are responsible for overall task performance including enabling the research within their areas to occur in a timely, efficient manner. Element, Project/Portfolio Lead Scientists will provide recommendations to their corresponding Managers regarding selection and performance of research studies and technology development projects within their purview.

A critical function of science management is to maintain the scientific integrity of the HRP. Therefore, all research and technology development tasks are reviewed for scientific merit, program relevance, and feasibility prior to implementation, and ongoing tasks are reviewed annually for progress and relevance to the research plan. The HRP Chief Scientist is responsible for implementing this comprehensive policy.

The HRP develops products and provides deliverables that enable NASA to manage human health and performance risks associated with planned space exploration missions: examples include the identification, definition and characterization of risks; maintenance of an evidence base compiling all of the data thought to be relevant to characterizing and mitigating the risks; recommending definitions of and refinements to standards issued by CHMO; products to monitor risk; products to reduce risk; and products to treat adverse health events. Figure 2 below illustrates the general relationships among these science management positions for the HRP.

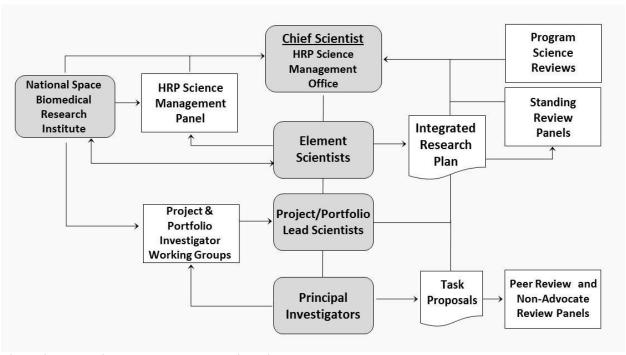


Figure 2. HRP science management relationships

3.1 CHIEF SCIENTIST

The HRP Chief Scientist is the senior science management official within the HRP and is the person delegated the responsibility for internal science management and coordination.

The responsibilities of the HRP Chief Scientist include, but are not limited to, the following duties.

Balance the HRP research portfolio:

- Provide the specifications for the contents of the HRP Integrated Research Plan (IRP) (HRP-47065) and review the content submissions to ensure that the HRP IRP contains sufficient information for scientific or technology review purposes
- Work with the HRP Elements to ensure that science activities are integrated across
 the program, are focused on the highest risks to crew health and performance in
 support of space exploration missions and that resources are used most efficiently, as
 science goals are obtained
- Review the research and technology development content in the HRP IRP, ensuring that this content is sound, integrated across the Elements, Projects and Portfolios as appropriate and reflects all of the Program's scientific needs

Coordinate research activities within the HRP:

- Coordinate, with recommendations from the appropriate Element, Project, or Portfolio Lead Scientists, the preparation and release of any scientific solicitations necessary to carry out the scientific objectives and goals of the HRP
- Manage and coordinate the schedule for HRP SRP activities and meetings

- Coordinate the schedule for the HRP science reviews
- Coordinate the development, review, maintenance and publication of the HRP Evidence Base
- Coordinate the annual HRP Investigators' Workshop to foster communication among HRP-sponsored investigators and across the HRP Elements and the NSBRI
- Serve as the Contracting Officer's Technical Representative for the NSBRI Cooperative Agreement
- Develop, with designated NSBRI representatives and HRP Element Scientists, plans for the full coordination of research activities between NASA and the NSBRI
- Solicit and coordinate inputs from other NASA Field Centers, as appropriate, in the execution of all of the HRP Chief Scientist's duties
- Coordinate joint activities with international partners through the Chief, HRP International Science Office.

Maintain the scientific integrity of the HRP:

- Chair the HRP Science Management Panel composed of the Element Scientists and other designated members
- Manage the Standing Review Panels (Section 7.2), including approval of the SRP statements of task and membership, in consultation with the SRP chairperson, and acceptance of resulting products
- Chair annual reviews of science progress (Section 7.3)
- Provide the Program Manager with a selection position on all scientific proposals, based on recommendations from the HRP Element, and Project or Portfolio Scientists and Managers, and ensure that they have completed the appropriate reviews
- Develop and manage the HRP's scientific merit review processes
- Work with the Element, and Project/Portfolio Lead Scientists to integrate science activities across the program
- Determine which Element should disposition any unsolicited proposals that are submitted to NASA (if no Element is appropriate, the HRP Chief Scientist will disposition the proposal)
- Ensure the existence of an unbiased, open process for evaluating the legitimacy of scientific dissents and supporting evidence (Section 10.0)
- Receive reports regarding real or perceived conflicts of interest from Element, Project and Portfolio Lead Scientists and others and determine the action to be taken in each case

Represent HRP positions to HEOMD, OCHMO, Vehicle/Mission Definition and Development Programs, as well as outside organizations:

- Serve as the primary scientific representative for the HRP with other NASA offices and programs external to the HRP, collaborating Federal programs and the general scientific community
- Present HRP's scientific program to HEOMD, other governmental entities and others, as appropriate (e.g., OCHMO or exploration vehicle programs)

Develop partnerships with the science community and international partners:

- Identify and cultivate strategic partnerships to leverage the HRP capabilities in support of space exploration missions
- Work with other domestic agencies to effectively integrate their research activities and those of the HRP
- Work (through ISO) with other international agencies to effectively integrate their research activities and those of the HRP
- Support the ISO Chief, as appropriate, in the International Space Life Sciences Working Group (ISLSWG) and all other formal bilateral or multilateral international working groups working collaboratively with the HRP
- Develop and maintain the HRP Cooperative Activities Profile, documenting the strategy and tactics related to joint programs and projects with other Federal agencies, with international space agency partners and other entities

Foster HRP science, advocating for science to organizations outside of HRP and enabling science within HRP:

- Support and coordinate, as needed, the presentation of HRP-sponsored research findings at appropriate national and international scientific and technological meetings
- Oversee the preparation of the section in the HRP Annual Report having to do with science activities of the HRP
- Compile and publish an annual report containing the list of HRP-sponsored research papers that have been published in peer-reviewed journals
- Coordinate the maintenance of HRP Tasks in the NASA Task Book (https://taskbook.nasaprs.com/Publication/welcome.cfm), an open, web-based description of all of the funded activities of the HRP
- Oversee the process used to periodically update the Human Research Roadmap (http://humanresearchroadmap.nasa.gov/) and the IRP
- Coordinate with the appropriate NASA legislative affairs offices the release of selection information
- Serve as a member of the Institutional Review Board (IRB)

The HRP Chief Scientist will be a senior scientist with an advanced degree in the life or medical

sciences, the social or behavioral sciences, the physical sciences, or the appropriate engineering sciences or the equivalent experience, and shall possess substantive experience in designing and conducting space life sciences experiments and in managing space flight related investigations and projects. The HRP Chief Scientist may not function as a scientific investigator within the HRP or any other external entity.

3.2 DEPUTY CHIEF SCIENTIST

The HRP Deputy Chief Scientist is responsible for assisting the HRP Chief Scientist in carrying out all of the duties assigned and any special duties assigned to the Deputy. In particular, the Deputy functions as the HRP Chief Scientist in his or her absence.

The HRP Deputy Chief Scientist will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, or the appropriate engineering sciences, and shall possess substantive experience in designing and conducting space life sciences experiments and in managing space flight related investigations and projects. The HRP Deputy Chief Scientist may not function as a scientific investigator within the HRP or any other external entity.

3.3 MANAGER, SCIENCE MANAGEMENT OFFICE

The HRP Science Management Office (SMO) Manager is responsible for supporting the HRP Chief Scientist in the execution of the responsibilities (Section 3.1). In so doing, the HRP SMO Manager assigns Office personnel to act as the HRP Chief Scientist's representative, or delegate, and coordinates their activities to make certain that the work is carried out efficiently. The HRP SMO Manager also develops and maintains the baseline SMO budget and schedule, integrated with the HRP Program Science Management (PSM) budget and schedule. The HRP SMO Manager leads budget formulation and integration of the SMO budget and supports integration with PSM input for the annual HRP Planning, Programming, Budgeting, and Execution (PPBE) process.

The manager of the SMO will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, the appropriate engineering sciences or the equivalent experience and shall possess experience in budget, contract and schedule management. The manager of the SMO may not function as a scientific investigator within the HRP or any other external entity.

3.4 CHIEF, INTERNATIONAL SCIENCE OFFICE

The Chief of the HRP International Science Office (ISO) represents HRP scientific interests across all International Partners (IP) by negotiating, coordinating, overseeing, and reporting the execution of all activities affecting human research coordination.

The responsibilities of the HRP ISO Chief include, but are not limited to, the following duties.

• Identify, with help from the HRP Chief Scientist, the primary human risks for exploration of joint interest to IP and develop strategies to coordinate research portfolios that maximize ISS utilization, space flight analog utilization, data sharing, subject sharing, and standardization of measurements

- Integrate the HRP assets with other IP assets into an international research portfolio maximizing efficiency
- Coordinate with multilateral (e.g., Multilateral Human Research Panel for Exploration - MHRPE, ISLSWG) and bilateral (e.g., Joint Working Group) implementation groups to develop unified strategic policies and processes
- Oversee the implementation of the ISS-12 human research portfolio based on integrated inputs from all ISS partners and maximize the value of the international human research effort for exploration to the goals and objectives of the HRP
- Develop the international fly-off plan for all ISS human research related to exploration
- Develop strategic and implementation plans for sharing of operational medical and human research data for ISS-12 including:
 - o Specific guidelines for handling of data and maintaining privacy
 - o Curation and analysis of data from all ISS partners
 - o Controlled access for interested and appropriate parties
 - Forum for timely sharing of research data prior to publication, to inform research next steps
 - Coordination of subject testing with medical monitoring requirements emphasizing commonality of measurement techniques wherever possible
- Develop guidelines for opening subject pools across the ISS Partners and provide recommendations for resolution of issues with compensation and liability with Partner subjects
- Develop guidelines for commonality of procedures and techniques to enable data pooling and comparison
- Work with the HRP ISS Medical Projects (ISSMP) and the Partner counterparts to identify enabling resource requirements
- Develop guidelines for the sharing of hardware across disciplines (including between medical operations and human research components of NASA and the IP) and across the IP to maximize human research return
- Develop guidelines to improve commonality of human research hardware across the ISS Partners
- Solicit ISS Program (ISSP) funding and support for implementation of common data, hardware, subject, methodology and ethics processes across the ISS partners
- Report to the ISSP and multilateral ISS management forums as needed
- Identify and track crew time requirements, including cost, for high return science for communication to ISSP
- Identify and work with representatives from agency stakeholder groups as needed, to include the ISSP, Medical Operations / Crew Health and Safety, Flight Crew Operations,

- Serve as the ISS Expert Working Group (IEWG) point of contact for HRP and agency human research
- Report IEWG and MHRPE activities and milestones

The HRP Chief of the ISO will be a senior scientist with a doctoral degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, or the appropriate engineering sciences, and shall possess substantive experience in designing and conducting space life sciences experiments and in managing space flight related investigations and projects with international partners. The HRP Chief of the ISO may not function as a scientific investigator within the HRP or any other external entity.

3.5 ELEMENT SCIENTIST

The HRP Element Scientist is responsible for the scientific components within the applicable Element.

The Element Scientist will:

- Ensure that the research carried out by the Element is organized to mitigate operationallyrelevant risks assigned to that Element by the Program and to develop countermeasures and/or technologies that support space exploration missions
- Develop and maintain the Element-specific portion of the HRP IRP, which clearly demonstrates the integration and coordination of the various projects within the Element, with other HRP Elements, the NSBRI or with other NASA organizations as necessary
- Integrate and coordinate the science performed within elements, portfolios and projects
- Support the meetings of the HRP Standing Review Panels
- Coordinate with the NSBRI to enable appropriate and complementary research activities
- Work closely with the HRP Element Manager to ensure that all Element scientific or technological activities are synchronized with the Element schedule, cost, and milestones and that the Element reviews are properly supported
- Provide scientific solicitation input to the HRP Chief Scientist as needed
- Review unsolicited proposals submitted to NASA for relevance to Element content
- Review directed task proposals (Section 6.1.3) for scientific relevance to the HRP IRP and forward those proposals to the HRP Chief Scientist
- Support the HRP Element Manager in developing a recommended Element science procurement plan taking into account the needs of the various Projects or Portfolios within the Element as appropriate
- Review the proposed selection recommendations for the Project or Portfolio and forward approved recommendations to the HRP Chief Scientist
- Ensure that all of the responsibilities of the Project/Portfolio Lead Scientist are fulfilled should one not be assigned

Serve as the element representative to the HRP Science Management Panel

The HRP Element Scientist will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, or the appropriate engineering sciences in the Element research area, and shall possess appropriate experience in designing and conducting experiments and in managing spaceflight related investigations and projects. The HRP Element Scientist may not function as a scientific investigator within the HRP or any other external entity. The HRP Manager may, on the recommendation of the HRP Chief Scientist, grant an exception to this rule if the scientific project is funded and managed by a different Element, or if it is otherwise in the best interests of the Government.

Selection of an HRP Element Scientist must have the approval of the HRP Program Manager and Chief Scientist.

3.6 DEPUTY ELEMENT SCIENTIST

The HRP Deputy Element Scientist is responsible for assisting the HRP Element Scientist in carrying out all of the duties assigned and any special duties assigned to the Deputy. In particular, the Deputy functions as the HRP Element Scientist in his or her absence.

The HRP Deputy Chief Scientist will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, or the appropriate engineering sciences, and shall possess substantive experience in designing and conducting space life sciences experiments and in managing space flight related investigations and projects. The HRP Deputy Chief Scientist may not function as a scientific investigator within the HRP or any other external entity.

3.7 PROJECT/PORTFOLIO LEAD SCIENTIST

The HRP Project/Portfolio Lead Scientist is the key person responsible for content of the scientific tasks in the Project or Portfolio, and, working closely with the Project or Portfolio Manager, ensures that all scientific or technology research tasks are synchronized with the schedule and cost plans. In some cases, a team of Lead Scientists will fulfill the roles and responsibilities of a Portfolio Lead Scientist.

The HRP Project/Portfolio Lead Scientist will be a discipline subject matter expert responsible for managing scientific tasks supporting the human, health and performance risk(s) within their discipline; multiple scientists may be assigned within a Project or Portfolio. The HRP Project/Portfolio Lead Scientist provides the general scientific interpretation of the Project or Portfolio activities as they relate to the HRP and NASA goals and objectives. The HRP Project/Portfolio Lead Scientist consults with the Element Scientist to execute this function.

The Project/Portfolio Lead Scientist will:

- Ensure that Project or Portfolio research is focused on mitigating high-priority, operationally-relevant risks and at developing countermeasures that support space exploration missions
- Develop and maintain the IRP assigned to the Project or Portfolio in coordination with the Element Scientist
- Develop an in-depth understanding of all investigations within the HRP Project or Portfolio, as well as NSBRI investigations and non-HRP funded investigations(e.g., SBIR, EPSCoR, other Federal funding sources, Section 2.4) that address assigned research gaps
- Maintain a strong liaison with the NSBRI to enable appropriately coordinated and complementary research activities by periodically conferring with appropriate NSBRI Team leadership
- Evaluate the progress that each task within the Project or Portfolio is making to close gaps and achieve its goals, and provide that evaluation to the Element and annually to the Standing Review Panel (Section 7.2)
- Evaluate the results and conclusions from each task within the Project or Portfolio to assess the impact to closing gaps or new countermeasures and provide the Project or Portfolio Manager, Element Scientist and Chief Scientist with recommendations for additional research closing the gap(s) or transitioning technology/information/countermeasures to the appropriate operational organization
- Chair the Project or Portfolio Investigator Working Groups (IWG) (Section 4.2), if one exists, containing the Principal Investigators (PI) from all Project or Portfolio investigations within the associated discipline
- Support the Project or Portfolio Manager in developing a recommended procurement plan for all types of scientific or technological activities necessary to carry out the Project or Portfolio
- Determine the need for, and coordinate the development of, directed task proposals seeking Portfolio or Project and Element management concurrence (Section 6.1.3)
- Recommend to the Element Scientist directed task proposals (Section 6.1.3) when they are complete and ready to be submitted for formal review
- Maintain current knowledge of all grants and contracts associated with Project or Portfolio milestones and deliverables
- Develop a selection recommendation for Project or Portfolio-related proposals after merit review, avoiding all real or perceived conflicts of interest (Section 3.7), unless specific selection decisions are mandated otherwise

As subject matter experts within their specific scientific discipline, an HRP Project/Portfolio Lead Scientists may not function as a scientific investigator within any of the Element's projects or tasks without the approval of the HRP Chief Scientist. When such a dual role is necessary,

care must be taken to avoid science management activities that produce real or perceived conflicts of interest including but not limited to participation in the development, evaluation, or selection process for any research solicitation. The HRP Program Manager may, on the recommendation of the HRP Chief Scientist, grant an exception to this rule if it is in the best interests of the Government and does not compete with other funded investigators within the Project or Portfolio. If any questions arise regarding conflict of interest, the HRP Element Scientist should contact the HRP Chief Scientist.

3.8 CONFLICT OF INTEREST

The HRP science management personnel must make every effort to avoid real or perceived conflicts of interest in carrying out their responsibilities. In general, this means that management personnel must avoid actions biased by personal gain, personal relationships, and conflicting management responsibilities. This includes the ability to directly determine the contents of research solicitations sponsored by HRP. It is the responsibility of each science manager within the HRP to identify any real or perceived conflict of interest and report it to the HRP Chief Scientist, who will determine the appropriate action to be taken. In addition, others within the HRP may report potential conflicts of interest to the HRP Chief Scientist for investigation and resolution.

To avoid conflicts of interest, the:

- HRP Chief Scientist, Deputy Chief Scientist, and Chief, ISO may not function as a scientific investigator or in any other science management position within the HRP
- HRP Element Scientist and Deputy may not function as a scientific investigator within
 any of the Element's projects nor simultaneously serve as a Project Scientist within the
 HRP. The approval of the HRP Chief Scientist is required when the dual role of Project
 Scientist is necessary
- HRP Project or Portfolio Lead Scientists may not function as a scientific investigator
 within any of the Element's projects or tasks without the approval of the HRP Chief
 Scientist. When such a dual role is necessary, care must be taken to avoid science
 management activities that produce real or perceived conflicts of interest including but
 not limited to participation in the development, evaluation, or selection process for any
 research solicitation.
- Standing Review Panels (Section 7.2) or their equivalent will be appointed and managed by the HRP Chief Scientist. These Panels will be asked to report any real or perceived conflicts of interest to the HRP Chief Scientist for resolution

Conflict of interest related to a Project/Portfolio or a proposal evaluation is addressed further in Section 6.4.

4.0 SCIENTIFIC COORDINATION PANELS

4.1 HRP SCIENCE MANAGEMENT PANEL

The purpose of the HRP Science Management Panel (SMP) is to facilitate HRP science management and ensure that an integrated science program is maintained. The HRP SMP should

advise the HRP Chief Scientist on the strategy to integrate Element science priorities, objectives, activities, and outcomes across the HRP, focusing on science products and deliverables that are operationally relevant. Details of the panel's operating procedures may be found in the Charter located in https://sa.jsc.nasa.gov/BPSCM/dashBoard/?boardName=SMP&action=showCharter.

4.2 PROJECT OR PORTFOLIO INVESTIGATOR WORKING GROUPS

If the HRP Project/Portfolio Lead Scientist decides that it is in the best interests of the Project or Portfolio, then an Investigator Working Group (IWG) may be established. The IWG is composed of all, or a discipline-specific subset, of the PIs within Project or Portfolio. The IWG is the primary working-level forum for research discussions and planning. At face-to-face IWG meetings, attended by the Project or Portfolio Manager, the PIs can exchange scientific and technological information concerning their investigations and have an opportunity to discuss the future research strategy with the other PIs and with the Project/Portfolio Lead and Element Scientists. In addition, it is expected that representatives of the ISS Medical Projects Element, if utilized by the Project or Portfolio, will attend the IWG meetings and report on any issues related to the implementation of flight or analog Project or Portfolio research tasks.

4.3 NASA-NSBRI STEERING COMMITTEE

In order to ensure that the activities of the NSBRI are fully integrated with the rest of the HRP, the NASA-NSBRI Steering Committee is established to coordinate both the acquisition and the execution of research activities between NASA and its NSBRI component. The permanent members of the NASA-NSBRI Steering Committee will consist of the following:

- NASA Members from the HRP
 - o Program Manager
 - Deputy Program Manager
 - Chief Scientist
 - Deputy Chief Scientist
 - Chief, International Science Office
 - Manager, Science Management Office
- NSBRI Members
 - o Chair, NSBRI Board of Directors
 - Director
 - Associate Director

Monthly meetings will be held at sites that alternate between JSC and the NSBRI. Other personnel may participate in the meetings, at the discretion of the permanent members.

5.0 RESEARCH PLANS

One of the major responsibilities of science management within the HRP is to participate in the development of the different research plans by ensuring that the research content in these plans meets the HRP requirements, as documented in the HRP Program Requirements Document

(PRD) (HRP-47052). The PRD describes an integration of customer and stakeholder needs, goals, and objectives that are relevant to the HRP and provides a traceable allocation of those needs to HRP Elements. Use of this PRD to guide research planning maintains the alignment of the HRP research program with those requirements.

The HRP research plans rely on knowledge and evidence gained through many years of multidisciplinary space-related research. This section summarizes the approach used to develop the HRP research plans and Appendix B provides further guidelines for producing these plans. The Element, Project and Portfolio Lead Scientists develop a research approach and notional plan to address the gaps and requirements.

Many of the annual activities involved in research plan development follow a schedule that is based, in large measure, on events contained in the annual cycle of activities followed by the HRP. A nominal template for that cycle is presented in Appendix C.

5.1 INTEGRATED RESEARCH PLAN

The HRP Integrated Research Plan (IRP) (HRP-47065) is a collection of most components of the five Element plans that looks across the Program to identify synergies and dependencies among the Elements and NSBRI for closure of risks and gaps. In effect, it is the combined strategic, tactical and implementation plan for research necessary to meet HRP requirements. It documents the time-phased approach required to address the research and technology development necessary to serve vehicle/mission definition and development programs and space exploration mission needs and timelines. It also defines research dependencies, such as the flight research that must be accomplished on the International Space Station.

The IRP should reflect that the HRP's activities are supporting the development of the existing and evolving human-system standards for health and human performance, and are addressing the complete set of risks assigned to the HRP. These standards provide a declaration of accepted medical risk from the deleterious health and performance effects of spaceflight, and will help focus and prioritize research and technology development efforts, providing target parameters for products and deliverables that will support the health maintenance of crews during space missions (Section 1.4). In addition, the standards identify spacecraft environmental and design limits that are required to sustain crew health and performance, and describe operational limits to requirements the system can impose on the crew members. Research within the HRP refines and narrows the uncertainties associated with standards and provides the evidence required to modify the standards, if necessary. Research also provides the pathway to appropriate countermeasures to mitigate risks.

Prior to each revision of the IRP, the HRP Science Management Office, in coordination with the Program Integration Office, issues guidance. Appendix B provides the basic format for the IRP and describes the general content of the required sections. The contents of this plan should clearly relate how the Program's requirements have led to the development of the current program portfolio. The HRP Control Board (HRPCB) approves the HRP IRP.

A web-based version of the HRP IRP is accessible via the Human Research Roadmap (HRR) at http://humanresearchroadmap.nasa.gov/.

5.2 EVIDENCE BASE

The HRP Evidence Base provides a current record of the state of knowledge from research and operations for each of the risks, written for the scientifically-educated, non-specialist reader and resides three repositories: the Human Research Roadmap, the Human Health and Performance in Space portal and the Human Research Wiki.

5.2.1 Human Research Roadmap

The HRP Human Research Roadmap contains a collection of HRP-approved Evidence Reports and citations for each individual risk contained within the HRP PRD (HRP-47052). The evidence reports are contained within the Human Research Roadmap website - http://humanresearchroadmap.nasa.gov/evidence/.

5.2.2 Human Health and Performance in Space portal

The Human Health and Performance in Space portal (http://en.wikipedia.org/wiki/Portal:Human Health and Performance in Space) is an informal collection of evidence describing the effects of spaceflight, travel and habitation on astronauts and other spaceflight participants. The topics presented within this portal stem from the HRP Evidence Base and are written for a scientifically-educated, non-specialist reader. Contributions and participation by medical professionals, scientists, researchers, students and the public atlarge is greatly encouraged.

5.2.3 Human Research Wiki

The Human Research Wiki (https://humanresearchwiki.jsc.nasa.gov) is an online collaborative environment, developed to enable the internal and external NASA research community to revise the evidence base for medical conditions which are of concern for spaceflight. The Wiki was developed by the Exploration Medical Capability (ExMC) Element within the HRP, and, at present, contains ExMC-specific evidence related to medical conditions that may occur during spaceflight and gap reports which outline existing gaps in either knowledge or technology that need to be addressed in order to enable safer exploration missions.

6.0 RESEARCH AND TECHNOLOGY PROPOSALS

It is the HRP's policy to utilize full and open competition for research and technology development investigations through annual research solicitations issued jointly by NASA and the NSBRI and to maintain a balance between selected intramural and extramural investigations. Figure 3 depicts the HRP procurement process. The HRP Unique Processes and Guidelines (UPCG) document (HRP-47069) contains detailed descriptions of procurement mechanisms supported by the HRP.

In the HRP, research and technology development proposals are of three types: solicited proposals, unsolicited proposals and directed task proposals. A Project's or Portfolio's research and technology development portfolio may contain activities generated from all three proposal types. All scientific and technology development activities within a Project or Portfolio must be based on one of these proposal types.

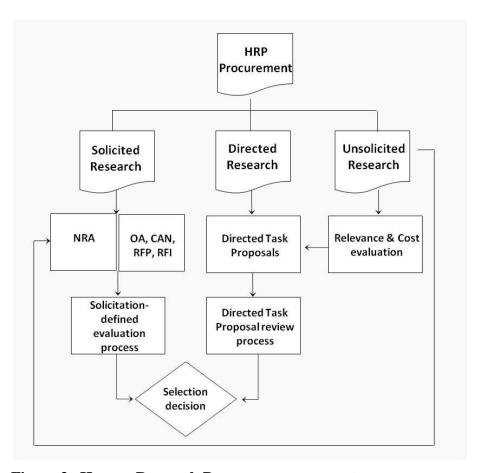


Figure 3. Human Research Program procurement process.

6.1 SOURCES OF PROPOSALS

6.1.1 Solicited Proposals

NASA generally uses Broad Agency Announcements (BAA) to solicit proposals for research and technology development investigations. Such BAA may take the form of Announcements of Opportunity (AO), NASA Research Announcements (NRA) or, less frequently, Cooperative Agreement Notices (CAN). In addition, for specific, well-defined research end points or tests, NASA may elect to use Request for Proposals (RFP) or a Request for Information (RFI). Preparation of solicitations for the HRP will be coordinated by the HRP Chief Scientist.

The HRP Chief Scientist has the responsibility to manage the Program's scientific merit review processes and resulting selection decisions and to provide the Program Manager with a selection position on all scientific proposals that have completed the appropriate reviews (Section 6.3).

6.1.1.1 Announcement of Opportunity

The AO is used to solicit and competitively select research investigations characterized as having a well-defined purpose and end product; for example, science investigations with hardware responsibility for a unique spaceflight mission, a program of flight missions or unique but large-cost non-flight programs. The AO can also be used for the selection of a science team for a

flight mission, with responsibility for data analysis and mission operations. Investigations selected through an AO can range in cost from a few hundred thousand dollars to several hundred million dollars. The key features of the AO process are:

- a. The opportunity is relatively unique
- b. The supporting budget is usually a unique line item authorized by Congress
- c. It is both a program-planning system and an acquisition system contained in one procedure

6.1.1.2 NASA Research Announcement

The NRA is used to solicit research that is characterized as being a part of the Program's ongoing approved research portfolio under the budgetary discretion of the HRP Program Manager. Normally, the HRP will issue at least two research announcements annually in partnership with the NSBRI, one for research in support of the Space Radiation Element and one for the remainder of the Program. In general, an NRA solicits for research and technology development investigations that are characterized as being of high relevance to Agency's interests in which a specific end product or service is not well-defined but left to the creativity of the proposer. The NRA is typically used to solicit and competitively select proposals for ongoing programs (although some may be singular in nature such as a data analysis program). The NRA contains two types of proposals – flagship and omnibus proposals. Flagship proposals result from applied, high-priority topics recommended by the Elements; typically, funding of ~\$350K per year for a duration of three years. Omnibus proposals may be on any risk and gap in the IRP and are designed to expedite research and technology development by resulting in delivery of enabling tools, techniques or knowledge; typically, funding of \$100K or less for a duration one-year or less.

6.1.1.3 Cooperative Agreement Notice

The CAN is used to solicit and competitively select proposals to support NASA program interests that require a high degree of cooperation between NASA and the selected institution. The scope of activities solicited by a CAN may be as modest as those through an NRA or as complex as those through an AO. The cooperative agreements awarded as a result of a CAN are similar to grants except that both NASA and the selected institution are required to provide resources, and both are involved in decisions related to the activities carried out by the selected institution.

6.1.1.4 Request for Proposals/Information

The HRP Elements that issue RFP or RFI are responsible for evaluation of proposals in accordance with the policies and procedures of the Federal Acquisition Regulation (FAR) and the NASA FAR Supplement (NFS). Please refer to FAR (https://www.acquisition.gov/far/) for details. The HRP Chief Scientist retains the option of observing, directly or through designees, any and all aspects of the RFP and RFI solicitation processes, in order to maintain appropriate programmatic oversight.

6.1.2 Unsolicited Proposals

An unsolicited proposal is defined as a written proposal that is submitted to NASA on the initiative of the submitter for the purpose of obtaining a NASA grant, contract or other

agreement and which is not submitted in response to a formal or informal request (other than an Agency request constituting a publicized general statement of needs). In general, NASA encourages the submission of unique and innovative unsolicited proposals which will further the Agency's mission. NASA may request unsolicited proposals be submitted to the during the annual NRA solicitation cycle as an omnibus proposal.

To be considered as a valid unsolicited proposal, a submission must:

- Be innovative and unique
- Be independently originated and developed by the proposer
- Be prepared without Government supervision, endorsement, direction, or direct Government involvement
- Include sufficient technical and cost detail to permit a determination that Government support could be worthwhile and the proposed work could benefit the agency's research and development or other mission responsibilities
- Not be an advance proposal for a known agency requirement that can be acquired by competitive methods

Note that the third item on the list above precludes NASA personnel and associated contractors from submitting "unsolicited" proposals. NASA personnel and associated contractors, however, have other means of presenting their ideas within the HRP UPCG (HRP-47069). Further details concerning unsolicited proposals are available in the Unsolicited Proposal Handbook (http://prod.nais.nasa.gov/pub/pub_library/unSol-Prop.html).

6.1.3 Directed Task Proposals

In certain situations, constraints on necessary research are incompatible with the use of the BAA described in 6.1.1. In these situations, where normal BAA solicitations are impractical, the HRP may utilize directed tasks to accomplish the desired research.

In order to utilize a directed task, at least one of the following criteria must be satisfied:

- Insufficient time for solicitation. In certain cases, NASA must define scientific activities in a short time (e.g., because of the emergence of new opportunities to carry out activities in space in support of space exploration). When this is the case, use of a directed task may be the only practical way to respond.
- Highly constrained research. In this case, the HRP requires constrained data gathering
 and analysis that is more appropriately obtained through a non-competitively developed
 proposal (e.g., the research task may involve extensive operational practices and
 associated operational personnel who must be heavily involved in the development of
 the study design).

Non-competitive proposals for directed tasks that satisfy the constraints may be guided by the Project/Portfolio Lead Scientist (or designee). However, in these cases, great care must be taken to avoid real or perceived conflict of interest in the development of such proposals (Section 3.7).

Directed task proposals may involve both intramural (NASA) and extramural investigators and may be for activities that will be accomplished in space, at NASA Field Centers or at universities or research institutions. Mechanisms should be in place to assure that the investigators are established scientists currently active in the research area and have the expertise and laboratory capability necessary to carry out the project. Generally, directed task proposals should involve both intramural and extramural investigators working as a team.

6.2 GENERAL PROPOSAL FORMAT

6.2.1 Solicited Proposal Format

The format for proposals submitted in response to BAA (AO, NRA, CAN) and other solicitations (RFP, RFI) is defined in the solicitation itself and submitters are expected to adhere strictly to that format. Otherwise, proposals may be deemed unresponsive and returned to the applicant. General guidelines and instructions do exist for preparing and submitting proposals in response to NASA solicitations (for NRA see the *Guidebook for Proposers Responding to a NASA Research Announcement* at http://www.hq.nasa.gov/office/procurement/nraguidebook/.) However, these instructions may be superseded by instructions contained in the solicitation and applicants should always follow the instructions in the BAA.

6.2.2 Unsolicited Proposal Format

There is no prescribed format for an unsolicited proposal, as long as it includes the following items:

- Transmittal Letter or Introductory Material
- Abstract
- Research Task Description
- Management Approach
- Personnel
- Facilities and Equipment
- Proposed Costs
- Other Matters

More information about each of these items is available in the Unsolicited Proposal Handbook – Section 6.1.2 - http://prod.nais.nasa.gov/pub/pub_library/unSol-Prop.html).

6.2.3 Directed Research Task Proposal Format

The HRP Unique Processes and Guidelines document (<u>HRP-47069</u>) contains detailed instructions on developing proposals for directed tasks.

6.3 PROPOSAL EVALUATION

6.3.1 Solicited Proposal Evaluation

All research solicitations must specify the research and technology development emphases, the criteria and specific evaluation factors used to evaluate the submitted proposals, and the method that will be followed for proposal evaluation. Although most solicitations include proposal scientific merit, relevance to the announcement, feasibility of implementation and cost as evaluation factors, other factors can also be included and the weight applied to each factor can differ from announcement to announcement. Evaluating proposals for merit or scientific quality may involve *ad hoc* scientific review panels established for the purpose of supporting a solicitation.

6.3.2 Unsolicited Proposal Evaluation

Unsolicited proposals can take two paths in the HRP. With the addition of omnibus proposals in the NRA, often, investigators will be referred to it as a resource for potential funding. In the event that an unsolicited proposal is submitted after submission deadlines have passed, the proposal will be examined by the HRP Chief Scientist who will determine which Element should consider it. If no Element is appropriate to carry out an initial review, then the HRP Chief Scientist dispositions the proposal and communicates with the applicant.

The Element Scientist, working with the Project/Portfolio Lead Scientists, will review the proposal and determines if the proposal is highly relevant to the IRP. If so, the Element Scientist forwards the proposal to the HRP Chief Scientist with an analysis supporting a recommendation that it be reviewed for merit by an appropriate non-advocate review (NAR) panel.

The HRP Chief Scientist reviews the Element recommendation, and if it warrants approval, coordinates the review with the NAR panel and transmits the review results to the appropriate HRP Element and Project/Portfolio Lead Scientists. Selection and funding by an Element depends on the merit of the proposal, the level of relevance, feasibility and cost (Section 6.5). Following the relevance and merit reviews, the Element communicates with the applicant and provides the results of these reviews.

6.3.3 Directed Research Task Proposal Evaluation

Directed task proposals are those that are highly relevant to the Portfolio which requested the proposal. Such proposals will be reviewed by an *ad hoc* non-advocate review panel managed by the HRP Chief Scientist, or by a lower level review managed by the Element or Project; the HRP UPCG (HRP-47069) details the non-advocate review process. Following the review, the results are provided to the HRP Chief Scientist, Element Scientist, Project/Portfolio Lead Scientist and Principal Investigator. Based on the evaluations and recommendations, the proposal may be approved without alteration, with alterations addressing the proposal's identified weaknesses, or the proposal may be disapproved. Selected proposals involving human or animal subjects must subsequently receive certification by an appropriate Institutional Review Board (IRB) or Animal Care and Use Committee (ACUC). Subsequently, selected proposals requesting spaceflight or analog resources must be evaluated for feasibility by the ISS Medical Projects (ISSMP).

6.4 CONFLICT OF INTEREST IN REVIEWS AND EVALUATIONS

Regardless of the type of review or evaluation selected, all personnel involved must avoid any possible real or perceived conflict of interest. A conflict of interest exists when a reviewer or evaluator has an interest in a Project, Portfolio, or research proposal that is likely to bias his or her evaluation.

If a reviewer or evaluator is also an investigator within a research discipline, then it is a clear conflict of interest for that person to make any recommendations or decisions regarding selection or funding of that research discipline. Such recommendations or decisions must be made independently and not involve the investigator in any way.

Other bases for conflict of interest include bias generated by personal relationships, longstanding professional disagreements, and multiple and conflicting management responsibilities, among others. Peer review panels will be instructed in the criteria used to determine whether a real or perceived conflict of interest exists; a reviewer who has a real conflict of interest with a Project, Portfolio, application or proposal may not participate in its review.

The HRP UPCG (HRP-47069) contains detailed information on criteria for reviewer conflict of interest.

6.5 PROPOSAL SELECTION AND FUNDING

Solicitations for research or technology development proposals specify the selection and funding process to be used to finally disposition the submissions. This includes identifying the selecting official, in addition to the evaluation factors, criteria and evaluation method to be applied. Applicants should see the specific solicitation for further information on selection and funding.

Once an unsolicited or directed task proposal is reviewed by the appropriate review panel, the Project/Portfolio Lead Scientist, in consultation with the Project or Portfolio Manager, prepares a selection recommendation, to be approved by the Element Scientist, which will include a budgetary component. Proposals requiring spaceflight must also be evaluated for flight feasibility by the ISSMP Element before the final selection recommendation is prepared (HRP UPCG (HRP-47069)). Proposals requiring a flight analog must be evaluated for feasibility by the Flight Analogs Project before the final selection recommendation is prepared. Proposals requiring use of the NASA Space Radiation Laboratory must be evaluated for feasibility by the Space Radiation Element before the final selection recommendation is prepared. In each case, the final selection recommendation is then submitted through the HRP Chief Scientist to the HRP Program Manager, the selecting official.

7.0 REVIEWS

7.1 DISCIPLINE SCIENCE REVIEW

Once a year, or whenever new evidence warrants it, the Element Scientist coordinates a schedule with the HRP Chief Scientist and the Project/Portfolio Lead Scientists to review any new evidence available to update the evidence report(s). These assessments will focus on how the evidence changes the current state of knowledge for: 1) human health and performance risks; 2)

gaps or uncertainties in the knowledge associated with those risks and relevant exploration design reference missions (DRM); and, 3) the countermeasure development plan.

7.2 STANDING REVIEW PANELS

The HRP Chief Scientist, with inputs from the Project/Portfolio Lead and Element Scientists, will establish a Standing Review Panel (SRP) for each research discipline within every HRP Element. In certain cases, such as the Human Health Countermeasures (HHC) Element, an integrated Element SRP composed of representatives of the discipline's SRP within the Element may also exist to advise the Element Scientist concerning integration of the multiple discipline activities. If such an Element panel exists, the review described below will begin with Element activities and then move to Project or Portfolio and discipline-specific activities.

A SRP will be maintained during the implementation phase of a HRP Project or Portfolio. To avoid any real or perceived conflict of interest, these panels will be coordinated and managed by the HRP Chief Scientist. Each panel will consist of primarily external discipline specialists, engineers and project management specialists, and non-conflicted NASA engineering and operational experts as needed, who will serve for a fixed period of from two to four years with staggered terms. The primary responsibility of the SRP is to review and comment on all scientific or technological aspects of a discipline through a review (whether face-to-face or by telecom) of the relevant sections of the HRP IRP and Evidence Base. This includes, but is not limited to the:

- Risk definition and mitigation gaps, and the individual tasks designed to strategically address these
- Research strategy that defines the relationship of the tasks to the gaps they are meant to answer
- Project/Portfolio Lead Scientist evaluation of the scientific progress of all ongoing tasks

In addition to the HRP IRP, the Panel should also be supplied with the limitations of the current research plan for the relevant discipline

The Panel will review research progress and activities and focus on strategy and tactical plans, as well as on a thorough discussion of the future procurement plan, including the need for specific tasks. All of the Panel's reviews will provide not only the strengths and weaknesses of plans but also a set of recommendations on how to address and correct the weaknesses, so that the resulting research plan is as strong as possible, given the constraints under which HRP must operate.

7.3 PROGRAM SCIENCE REVIEW

Each year, at the discretion of the Program Manager, the HRP Chief Scientist, working closely with the Element and Project/Portfolio Lead Scientists, will provide an overview of the entire research portfolio to the HRP Program Manager, pointing out significant accomplishments, risks and challenges to the current plan, traceability of activities to the HRP Program Requirements Document (HRP-47052), and the gaps that remain to be addressed. This internal Program Science Review by the HRP Chief Scientist and Program Manager will be coordinated with

NASA's annual budgetary planning schedule and will be based on established criteria for the evaluation of HRP research in terms of risk mitigation and operational relevance. Preliminary criteria include: (1) the documentation of new scientific evidence that further mitigates stated risks or identifies new ones; (2) the advancement of Technology Readiness or Countermeasure Readiness Levels; and (3) the delivery of tangible products that are accepted by HRP customers.

The Program Science Review will include an assessment of the need for continuation, modification, expansion or termination of scientific investigations based on evolving results, evidence and program needs.

7.4 ANNUAL HRP INVESTIGATORS WORKSHOP

Each year, the HRP will hold an Investigators Workshop coordinated by the HRP Chief Scientist, allowing HRP-sponsored investigators and managers the opportunity to seek collaborations and integrate and communicate the results of their research activities to HRP's stakeholders (space medicine, astronauts, and NASA management) and its Agency customers (e.g., HEOMD and OCHMO).

7.5 PROGRAM STATUS REVIEW

Every two years, the Agency conducts an independent assessment of the HRP's continuing relevance to the Agency's Strategic Plan and its performance to the approved technical baseline, budget, schedule, and all risks and their mitigation plans. The Program Status Review (PSR) provides Agency management with an independent assessment of HRP's compliance with Agency management policies and procedures and readiness to continue with implementation. The PSR is designed to review the HRP's management approach, not specific scientific content.

7.6 RISK AND EVIDENCE REVIEW

At least every five years, a review will be conducted of the current risks assigned to the HRP, and of the evidence that forms the basis for the risks. This review will result in a publicly available document describing the level of evidence supporting each risk. The document provides recommendations for the HRP to consider, and may or may not be adopted by the HRP.

7.7 PRE-DELIVERY ACCEPTANCE REVIEW

As stated in the Program Plan (HRP-47051), the HRP will ensure validation of all HRP research and technology development deliverables, such as standards updates, new technologies, countermeasures, design models and risk projection models. The HRP Chief Scientist is responsible for conducting a pre-delivery acceptance review in order to validate a product prior to delivery to an external customer. The HRP Chief Scientist is responsible for establishing validation guidelines and approving validation plans for each type of deliverable, with support from the applicable Element Scientist. If the deliverable is identified in a Customer Supplier Agreement (CSA), the acceptance review must verify all deliverable requirements specified in the agreement are met.

8.0 DATA MANAGEMENT

Data management, including issues related to archiving and accessing data and physical samples from ground and flight studies, is an important component of the HRP. In accordance with the National Aeronautics and Space Act of 1958, as amended, all research data gathered under the HRP will be made publicly available in a non-attributable form. HRP policy dictates this will take place within one year of the completion of data collection.

8.1 LIFE SCIENCES DATA ARCHIVE

Research data from the HRP research and technology development tasks is collected and stored in the research data repository - Life Sciences Data Archive (LSDA). The LSDA prepares and maintains a Data Management Plan (DMP) describing how the scientific data generated by life sciences experiments are managed. This plan defines how the LSDA manages data collection, storage, preservation, and data distribution in support of the HRP. All data collected through research programs sponsored by NASA are considered public. Data produced from NASA-funded life sciences research must be submitted to NASA and are archived in the NASA LSDA for the benefit of the greater research and operational spaceflight community.

The appropriate HRP Element Scientist shall work with the LSDA to outline specific archiving requirements and develop an LSDA Data Submission Agreement (DSA). These requirements shall include which research data are to be included, the format of the data, and the timeframe in which the data is expected to be submitted for archiving.

8.2 ELEMENT DATA MANAGEMENT PLAN

Each HRP Element prepares and maintains a Data Management Plan describing how the scientific data generated within the Element are managed. This plan is a component of the HRP IRP. The plan includes a definition of data rights and services and access to samples, as appropriate and describes the general structure, function and operation of the distributed data, physical sample and information management system that is necessary to serve the needs of the research community while preserving the rights of the subjects.

The HRP Element Data Management Plan will adhere to the requirements of NPD 2200.1B (Management of NASA Scientific and Technical Information), NPR 2200.2B (Requirements for Documentation, Approval, and Dissemination of NASA Scientific and Technical Information), and NPR 1441.1D (NASA Records Retention Schedules), as applicable to science data.

9.0 TECHNOLOGY DEVELOPMENT PROCESS

Technology is the development, usage and knowledge of tools, techniques, crafts, systems or methods of organization in order to solve a problem or serve a purpose. As described in the HRP Program Plan (HRP-47051), critical human systems technologies will normally be developed within the HRP from Technology Readiness Level (TRL) up to 6 and will stem from HRP Element and NSBRI basic and applied research.

Since these technologies are developed to satisfy requirements for medical care, environmental control, human factors, etc., it is important that the technology gaps are clearly identified, the most cost effective approach selected and the customers for these technologies agree that the technologies are appropriate. Therefore, it is essential that formal Customer Supplier Agreements (CSA) (Section 9.2) be developed at the initiation of the development process to ensure that the technology deliverables meet the customer's requirements.

The HRP technology development process begins with the identification of technology needs and gaps. Technology needs are derived from sources such as the customer, mission concept studies or DRM, technology roadmaps and associated system analysis, or technology gap analysis. Examples include, but are not limited to, the following HRP deliverables as listed in the HRP IRP: systems solutions, prototype/hardware, protocols, or software. Once identified, the responsible Element, Project or Portfolio will perform a complete technology market analysis to identify potential sources for the technologies and the current TRL and prepare a recommended technology development plan. Selected developments will undergo appropriate merit reviews prior to Authority to Proceed (ATP).

The HRP technology development process ends with the handover to the customer of technology deliverables for continued development to higher TRLs and ultimate insertion into the associated customer program.

9.1 TECHNOLOGY DEVELOPMENT PROJECTS

HRP Technology Development (TD), and infusion, is a component of each Element's specific research plan. These plans should outline the strategy for the entire lifecycle of the technology development activity, not just the period for which the HRP is financially responsible. The plans should include (at least) the following components:

- A clear description and basis for the technology need and chosen approach
- The planned method for assessment of the current state of technology
- The rationale and method for make versus buy decisions
- How the TD activity aligns with the HRP Program Plan and Program Requirements
 Document
- A defined list of customers and plan to present to/discuss with them the proposed technology development
- Technology needs and requirements that the technology addresses
- The implementation alternatives to meeting the requirement that were evaluated
- The planned method of project implementation
- Any external requirements that should be taken into account in the technology development or those that present particular challenges to bringing the technology to its ultimate application (such as environmental requirements for the operations environment in which the technology will work)
- The anticipated TRL level to which the technology will be developed

- Identification of key performance parameters throughout the technology lifecycle (special key performance parameters that the technology must meet when at a higher TRL level, but that affect the earlier technology development, should be identified)
- The anticipated method of infusion of the technology into operations (anticipated method, and timeframe for transfer of management and financial responsibility for operational development)
- A plan for synergies or partnerships with any other HRP technology projects with similar requirements
- Reviews to be held with the customer and other key requirement owners throughout the life-cycle of the TD
- Method of independent assessment and customer review at the time of the technology hand-off to the customer for operational development

The NSBRI strategic goals for TD, in keeping with the mutual human health exploration risk reduction goals and synergism between NASA and NSBRI, are described in the NSBRI Strategic Plan (http://www.nsbri.org/default/About/NSBRI_strategic_plan.pdf).

9.2 CUSTOMER SUPPLIER AGREEMENTS

A CSA is established to document the responsibilities of both the customer (typically external to HRP) and the supplier (an HRP Element) of a research or technology development product prior to initiation. These agreements are essential in defining expected use, operational concepts, and customer expectations and requirements for the projected technology development through all lifecycle phases. The CSA may also describe the responsibilities that the supplier has for transitioning the technology to the customer and assisting the infusion of the technology into their program.

For those customers who have their own baseline requirements for a CSA, the customer's template may be used per the guidance in the HRP UPCG (HRP-47069).

The CSA process is as follows:

- Identify the customer(s), suppliers and stakeholders
- Define customer expectations and definitive requirements
- Establish the technology operations concept and support strategies
- Analyze expectation statements for measures of effectiveness
- Validate that the defined requirements reflect traceability (per NASA NRP 7123.1 NASA Systems Engineering Process and Requirement, if applicable)
- Obtain customer commitments to the validated set of expectations and requirements
- Baseline customer expectations and derived requirements

The Element Manager will determine, based on the complexity of the deliverables for a particular customer, if an individual deliverable CSA is needed or if one comprehensive CSA will be sufficient.

The Element Manager, will also identify the customers and stakeholders and determine the level of customer management approval required, which is dependent on the complexity of the element technology development activity. A signed CSA should be obtained before the technology development effort begins, and is required whenever a deliverable from the HRP to and external customer will result.

Note: There may be some cases where a CSA is not feasible and therefore waived by the HRP. For example, a risk is not yet documented by a customer and the Element Manager can provide evidence to the HRP that: (1) a requirement is forthcoming, and (2) that the proposed TD project is the only way to address the requirement.

9.3 TECHNICAL REVIEWS

HRP Technology Development activities will go through merit reviews prior to ATP as well as the standard HRP scientific and status reviews listed in Section 7 of this document as a part of the HRP project they are supporting. For example, the Standing Review Panel reviews all appropriate scientific or technological aspects of a Project or Portfolio and the Program Science Review reviews the advancement of Technology Readiness or Countermeasure Readiness Levels (Appendix B).

Other reviews, in mutual agreement with the customer and documented in the CSA, should be held in an appropriate frequency to keep the customer apprised of the continuing progress of the technology development and for the exchange of important information such as evolving changes in requirements.

10.0 DISSENTING SCIENTIFIC OPINION

This section defines a method for presenting a dissenting scientific opinion regarding a risk within scope of the HRP. The science portfolio of the HRP is developed from risk profiles based on scientific evidence and non-experimental (i.e., anecdotal or clinical) flight data. Decisions on the existence and/or seriousness of risks, of the adequacy of evidence supporting the risks and on the robustness of the resulting conclusions from the scientific and non-experimental flight data can be disputed. The submission of a written dissenting scientific opinion is the intended route for addressing and resolving these disputes.

A scientific dissent does not address whether one agrees with management of risk or resources, but rather whether or not the science supporting the risk assessment is sound, reliable, defensible, and accurate. The HRP Chief Scientist will be responsible for ensuring an unbiased, open process for evaluating the legitimacy of scientific dissents and supporting evidence.

10.1 PROCESS FOR ADDRESSING SCIENTIFIC DISSENT

Normal HRP processes and required reviews should enable discussion of the dissenting opinion/ alternative point of view should be addressed at the lowest level forum first and progress to the

next higher level only if the initiator feels their concern was not properly considered or addressed. If not satisfied with the decision in the lower level forum, the initiator of the dissenting opinion should discuss the matter with the responsible HRP Project, Lead or Element Scientist. In the event the initiator of the dissenting scientific opinion believes their perspective needs further consideration, the scientific dissent is written and submitted to the HRP Chief Scientist for discussion and review. The HRP Chief Scientist will not consider a dissenting opinion unless it has been through the appropriate lower-level discussions.

The template for developing the written dissenting scientific opinion is available in Appendix D. All historical information related to the dissenting opinion should be included in the written dissenting opinion package (i.e., meeting minutes). The written dissent submitted to the HRP Chief Scientist will be the final level of consideration for the dissent within the HRP.

The dissenting opinion in written form will be assessed using a systematic evaluation of the evidence supporting the dissent. The dissenting opinion will be evaluated for clarity, relevant supporting evidence, and credible, realistic treatment of scientific uncertainties by the HRP Chief Scientist and members of the Science Management Panel. The written dissent has the responsibility to inform the reviewers of any potential impacts to human health or performance if the dissenting scientific opinion is not investigated.

All assessments and final comments to the formal written dissent are to be completed in a timely manner, considered to be within six weeks from the acceptance of the dissent to the final written disposition at each level of panel review or advisory review.

10.2 RESOLUTION OF SCIENTIFIC DISSENT

The final disposition of the matter will include the rendered opinion (agreed with dissent, disagree with dissent, need more information), the rationale for the decision, the evidence and references supporting the rendered opinion, and a list of those who reviewed the dissent and their affiliation. If any of the reviewers have a real or perceived conflict of interest or bias, then this is noted and explained.

If the initiator of the scientific dissent does not agree with the HRP Chief Scientist's final disposition, he/she may elevate the dissent utilizing the current NASA Governance Model, the Health and Medical Technical Authority (HMTA) process. The HRP Science Management Office or the Center specific Ombudsman Office can provide guidance for how to access the Health and Medical Technical Authority.

APPENDICES

APPENDIX A. RESEARCH CATEGORY DEFINITIONS

Applied Research and Technology Development Activities

Applied research and technology development activities are those research investigations that are designed to provide the knowledge and data necessary to inform system standards for health and performance, as well as enable definition and validation of risk mitigation strategies. HRP technology development activities consist of those investigations focused on the development of new or improved technologies and capabilities, including advanced technologies involved in the maintenance and management of crew health and performance. For example, equipment to manage the medical risks must be smaller and more reliable than the current state of the art. HRP research and technology development also seeks to develop capabilities to reduce the risk of mission-impacting human performance issues.

Core Service Activities

The purpose of the core services activities is to provide support to the investigations being carried out within the applied research and technology development components. This approach allows for more efficient management of core capabilities necessary to enable the needed flight and ground research. HRP core service activities fall within the ISS Medical Projects Element.

APPENDIX B. COUNTERMEASURE AND TECHNOLOGY READINESS LEVELS

Countermeasure Readiness Levels (CRL)

Technology Readiness Levels (TRL)

(CKL)		
Phenomenon observed and reported. Problem defined.	CRL/TRL	Basic principles observed and reported: Transition from scientific research to applied research. Essential characteristics and behaviors of systems and architectures.
Hypothesis formed preliminary studies to define parameters. Demonstrate feasibility.	CRL/TRL 2	Technology concept and/or application formulated: Applied research. Theory and scientific principles are focused on specific application area to define the concept. Characteristics of the application are described.
Validated hypothesis. Understanding of scientific processes underlying problem.	CRL/TRL	Analytical and experimental critical function and/or characteristic proof-of concept: Proof of concept validation. Active Research and Development (R&D) is initiated with analytical and laboratory studies.
Formulation of countermeasures concept based on understanding of phenomenon.	CRL/TRL 4	Component/subsystem validation in laboratory environment: Standalone prototyping implementation and test. Integration of technology elements.
Proof of concept testing and initial demonstration of feasibility and efficacy.	CRL/TRL 5	System/subsystem/component validation in relevant environment: Thorough testing of prototyping in representative environment. Basic technology elements integrated with reasonably realistic supporting elements.
Laboratory/clinical testing of potential countermeasure in subjects to demonstrate efficacy of concept.	CRL/TRL	System/subsystem model or prototyping demonstration in a relevant end-to-end environment (ground or space): Prototyping implementations on full-scale realistic problems. Partially integrated with existing systems.
Evaluation with human subjects in controlled laboratory simulating operational spaceflight environment.	CRL/TRL 7	System prototyping demonstration in an operational environment (ground or space): System prototyping demonstration in operational environment. System is at or near scale of the operational system, with most functions available for demonstration and test.
Validation with human subjects in actual operational spaceflight to demonstrate efficacy and operational feasibility.	CRL/TRL 8	Actual system completed and "mission qualified" through test and demonstration in an operational environment (ground or space): End of system development. Fully integrated with operational hardware and software systems. Most user documentation, training documentation, and maintenance documentation completed.
Countermeasure fully flight- tested and ready for implementation.	CRL/TRL 9	Actual system "mission proven" through successful mission operations (ground or space): Fully integrated with operational hardware/software systems. Actual system has been thoroughly demonstrated and tested in its operational environment.

APPENDIX C. GENERAL GUIDELINES FOR DEVELOPING THE INTEGRATED RESEARCH PLAN

These guidelines contain a suggested format for the presentation of the various research plans within the HRP. The guidelines are general and may be adapted to fit the particular needs of the actual elements or program.

> EXECUTIVE SUMMARY

Provides an executive summary of the Integrated Research Plan

> INTRODUCTION and BACKGROUND

Provides the background and context of the HRP's research program in the context of NASA's space exploration missions and describes the requirements that are HRP's responsibility

> RISKS

Each text description has a statement of the risk. These statements are verbatim from the PRD, and are reprinted in the HRP IRP as a matter of convenience for the reader. With the title of each risk, the criticality is given. Criticality ratings correspond to the criteria established in the HRP PRD.

> CONTEXT

This section provides the context of how the research plan is built for that risk and describes the need for the research at a very high level.

> OPERATIONAL RELEVANCE

In this paragraph, a description of the relevance to the space exploration mission is given.

> STRATEGY FOR MITIGATION

The approach strategy for the mitigation of the risk is outlined in this section. For instance, the strategy may be to first determine space normal physiology, then identify specific countermeasures.

> GAPS

Gaps in our knowledge or in the evidence base exist for each risk. These gaps have several different forms. A gap may exist in our evidence base, which leaves greater uncertainty regarding the likelihood of the risk. A gap may exist in the identification of the appropriate countermeasure. For other risks, the gap may be in the flight validation of the appropriate countermeasure.

> TASKS

For each gap, the task(s) required to fill that gap are listed. Each task is named and a short description is given. In some cases, a task can address multiple gaps across multiple risks. In addition, the project responsible for implementation of the task is listed, along with the anticipated procurement method.

> DELIVERABLES

A deliverable is an end product, or products, agreed to by the customer and supplier. The supplier is the primary provider of the deliverable (s). The customer is the primary recipient that takes ownership of the deliverable(s). A stakeholder is an entity with buy-in and interest in deliverable(s).

APPENDIX D. TEMPLATE FOR THE HRP ANNUAL CYCLE

The management activities of the HRP repeat annually because the Federal budget system follows an annual cycle, with the President's budget submission to Congress during the first quarter of each calendar year. That budget is for the next Fiscal Year (October 1 - September 30). Thus, each year, NASA must prepare a revised budget and submit it to the Office of Management and Budget during the third quarter of the calendar year. This means that each component within NASA, including the HRP, must prepare a revised budget during the second quarter of the calendar year. This annual cycle of budget preparation and submission defines a fixed point in the management activities of the HRP. A nominal annual cycle of related science management and procurement events is presented in Figure D-1.

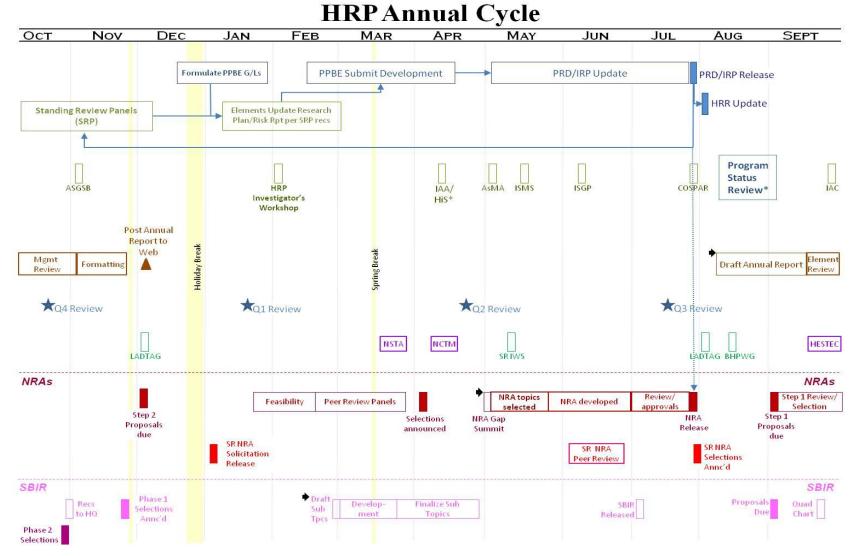


Figure D-1. Template for annual cycle of events within the HRP.

Note: This is a representative template only and is subject to change or revision as events unfold throughout the year.

Figure D-1 includes the following abbreviations:

ASGSB	American Society for Gravitational and Space Biology	IWG	Investigator Working Group
AsMA	Aerospace Medical Association	LADTAG	Lunar Airborne Dust Toxicity Assessment Group
BHPWG	Behavioral Health and Performance Working Group	NCTM	National Council of Teachers in Mathematics
COSPAR	Committee on Space Research	NRA	NASA Research Announcement
EM	Element Manager	NSBRI	National Space Biomedical Research Institute
FAP	Flight Analogs Project	NSTA	National Science Teachers Association
G/L	Guidelines	PM	Program Manager
HESTEC	Hispanic, Engineering, Science, and Technology	PPBE	Planning, Programming, Budgeting, and Execution
HiS	Humans in Space [conference]	PRD	Program Requirements Document
HRP	Human Research Program	Qn	Government Fiscal Year (Quarter 1, 2, 3, or 4)
HRR	Human Research Roadmap	SBIR	Small Business Innovative Research
IAA	International Academy of Astronautics	SMO	Science Management Office
IAC	International Astronautical Congress	SR	Space Radiation
IRP	Integrated Research Plan	SR IWS	Space Radiation Investigator's Workshop
ISGP	International Society for Gravitational Physiology	SRP	Standing Review Panel
ISMS	International Space Medicine Summit		-

APPENDIX E. TEMPLATE FOR WRITTEN DISSENTING SCIENTIFIC OPINION

The following is guidance for developing a written scientific dissenting opinion.

1.0 Executive Summary

Provide a half page executive summary of the report:

- Problem/Issue requiring a decision (1 sentence),
- Identify the decision makers/stakeholders (Project/Portfolio Lead Scientist, Element Scientist and other related authorities),
- Brief summary of the dissenting scientific opinion
- Recommendation (1 sentence).

2.0 Problem/Issue Description

Describe fully the data supporting the dissenting scientific argument. Provide background, history, and a high quality, accurate, clear, and relevant discussion in support of the dissenting scientific opinion. A flawed study addressing critical issues is not an acceptable alternative to a high quality study. The description should demonstrate the data being submitted in support of the dissenting scientific opinion is relevant, reliable, reproducible, and robust.

Background should consist primarily of evidence supporting the dissenting opinion, with limited assumptions, but also include the potential impacts to crew health and performance. Use the background section to outline scientific principles used in subsequent analyses or discussion. The supporting evidence included in the discussion must be organized in a concise manner to enable a clear, consistent evaluation of the data.

Provide the history of where the dissenting opinion was discussed previously. Include which boards, working groups, review panels heard the alternative point of view and what the comments or disposition of the opinion was at those previous levels.

3.0 Potential Impact

Discuss the potential impacts to Project, Portfolio, Element or Program, validated safety issues, and likely outcomes if the recommendation is not accepted.

4.0 Recommendation

Describe the recommendation (with rationale) that is being made to the Review Authorities.

5.0 References

Document all references. References may include minutes of boards and panels, e-mails, personal communications, and other correspondence discussed in Section 3.

APPENDIX F. LIST OF ACRONYMS

ACUC Animal Care and Use Committee AO Announcement of Opportunity

ATP Authority to Proceed

BAA Broad Agency Announcement
BHP Behavioral Health and Performance
CAN Cooperative Agreement Notice
CHMO Chief Health and Medical Officer

CMO Chief Medical Officer

CRL Countermeasure Readiness Level
CSA Customer Supplier Agreement

DMP Data Management Plan
DRM Design Reference Mission
DSA Data Submission Agreement

EARD Exploration Architecture Requirements Document

EPSCoR Experimental Program to Stimulate Competitive Research

ESMD Exploration Systems Mission Directorate

ExMC Exploration Medical Capability

HEOMD Human Exploration and Operations Mission Directorate

HHC Human Health Countermeasures

HH&P Human Health and Performance Directorate

HIDH Human Interface Design Handbook

HMTA Health and Medical Technical Authority

HRP Human Research Program

HRPCB Human Research Program Control Board

HRR Human Research Roadmap IEWG ISS Expert Working Group

IP International Partners

IRB Institutional Review Board IRP Integrated Research Plan

ISLSWG International Space Life Sciences Working Group

ISO International Science Office ISS International Space Station

ISSP International Space Station Program

ISSMP ISS Medical Projects

IWG Investigator Working GroupJSC Johnson Space CenterLSDA Life Science Data Archive

MHRPE Multilateral Human Research Panel for Exploration

NAR Non-Advocate Review

NASA National Aeronautics and Space Administration

NPD NASA Policy Directive

NPR NASA Procedural Requirement NRA NASA Research Announcement

NSBRI National Space Biomedical Research Institute
OCHMO Office of the Chief Health and Medical Officer
PPBE Planning, Programming, Budgeting, and Execution

PRD Program Requirements Document
PSM Program Science Management

PSR Program Status Review
RFP Request for Proposals
RFI Request for Information
R&T Research and Technology

SBIR Small Business Innovative Research

SLPSRA Space Life and Physical Science Research and Applications

SLSD Space Life Sciences Directorate SMO Science Management Office SMP Science Management Panel

STD Standard

STTR Small Business Technology Transfer

TD Technology Development
TRL Technology Readiness Level